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|-------------------------------|------------------------|---------------------|--|
| <b>Notice of Allowability</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                               | 09/943,380             | MULHOLLAND ET AL.   |  |
|                               | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                               | Ann Y. Lam             | 1641                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed January 23, 2007.
2. ☒ The allowed claim(s) is/are 1-6, 8-64 and 73-79.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>20070211</u></li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
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### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael Farber on February 12, 2007.

The application has been amended as follows:

In Claim 33, line 11, replace "urethra" with –urinary tract--.

In Claim 35, line 11, replace "urethra" with –urinary tract--.

In Claim 45, line 2, delete "said portion of".

In Claim 76, line 13, replace "urethra" with –urinary tract--.

In Claim 76, line 19, delete the second "being".

The following is an examiner's statement of reasons for allowance: the prior art does not teach or suggest a suppository having 1) a non-meltable base member that is wider than a meltable portion or is ellipsoid having a major axis perpendicular to the longitudinal axis of a reinforcement member, 2) a non-meltable reinforcement member, and 3) a meltable taper that occupies substantially the extent of the meltable portion from the second end of the reinforcement to the first end of the reinforcement, wherein the first end is attached to the base member. More specifically as to the art of record,

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neither DeSushko, 1,767,785, nor D'Augustine, 6,416,779, teach or suggest that the taper of the meltable portion occupies substantially the extent of the meltable portion from the second end of the reinforcement to the first end of the reinforcement, wherein the first end is attached to the base member. Also, neither Patent 6,464,670 to Mulholland, nor D'Augustine 6,416,779, teach a non-meltable base member that is either 1) wider than the meltable portion, or 2) ellipsoid having a major axis perpendicular to the longitudinal axis of the reinforcement. While Patent 6,464,670 (and similarly WO 00/13721 cited in Applicants' IDS filed 1/24/02) discloses an element (16) which may be considered a base member having the dimensions currently claimed by Applicants, element (16) however is not "non-meltable", and there is no suggestion in the prior art to make element (16) non-meltable.

Moreover, Examiner's interpretation of the term "non-meltable" is as follows. While Applicants do not explicitly give a definition for "non-meltable", Applicants do state in the specification on page 11, lines 20-22: "As used herein, the term "melt" means to be changed from a solid to a liquid state (i.e. undergo liquifaction) by the application of heat, pressure, or both. When installed in the urethra, the meltable portion of the suppository invention undergoes liquifaction." Based on Applicants' specification and the art of suppositories, it is understood that "non-meltable" means to not be changed from a solid to a liquid state during normal use of the suppository, i.e., when inserted into a human body (or more specifically, the urethra of a live, human female), and thus this understanding of the term "non-meltable" is interpreted by Examiner as the meaning of "non-meltable" as recited by Applicants in the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Handwritten signature of Ann Yen Lam in black ink, with the date 2/12/07 written to the right of the signature.

ANN YEN LAM  
PATENT EXAMINER